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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,506	11/01/2005	Craig A. Townsend	029869.00001-UA01	2647
85938	7590	12/31/2009		
Fox Rothschild LLP Phlla, Biotech Group 2000 Market Street Philadelphia, PA 19103			EXAMINER THOMAS, TIMOTHY P	
			ART UNIT 1628	PAPER NUMBER
			MAIL DATE 12/31/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/520,506	<b>Applicant(s)</b> TOWNSEND ET AL.	
	<b>Examiner</b> TIMOTHY P. THOMAS	<b>Art Unit</b> 1628	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 14-18 and 28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 14-18 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

1. The species under examination is expanded to include compound VIII.

***Response to Arguments***

2. Applicants' arguments, filed 9/17/2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

3. Applicant's arguments, see p. 6, filed 9/17/2009, with respect to the rejection under 35 USC 103 have been fully considered and are persuasive. The rejection of claims 1-4, 14-18 and 28 under 35 U.S.C. 103(a) as obvious over Kuhajda, et al. (US 2006/0247302 A1, which qualifies as prior art under 35 USC 102(e)) has been withdrawn.

The establishment of an obligation of assignment to the same entity at the time of the instant invention is effective to overcome this rejection basis.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

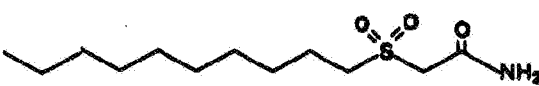

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-4, 14-18 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Townsend et al. (WO 99/10321 A2; 1999; cited in a prior Office Action).

Townsend teaches a method for treating a mycobacterial infection by administering to an animal a pharmaceutical composition containing a compound with the formula  $R-SO_n-Z-CO-Y$ , which may be used to inhibit growth of mycobacterium, including *Mycobacterium tuberculosis* (abstract); treatment of human patients (p. 8, line

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10) and animals (claim 8), including cattle and sheep (p. 8, lines 7-8), compounds taught include SI-73 and HIII-302 (p. 20, Table 1), depicted here:

Compound #		MTB	BCG	MAI
SI-73		3.12		12.50
HIII-302		>25		

Amounts taught include amounts to achieve serum concentrations from about 1 ng to about 10 µg/mL, typically 0.1 to 10 µg/mL (p. 9, lines 5-6).

Townsend does not teach the compound of Formula VIII of instant claims 1 and 15. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify SI-73, by substituting the  $-\text{CH}_2\text{C}(\text{O})\text{OCH}_3$  moiety from the right end of compound HIII-302 for the terminal H of the  $-\text{NH}_2$  moiety of SI-73, giving instant compound VIII, and to administer this obvious compound in the treatment of a human or animal, including to cattle or sheep infected with *Mycobacterium tuberculosis*, giving the instantly claimed methods. The motivation would have been by starting with the most effective compound taught in Table 1 (with lowest MTB), SI-73, then modifying this compound, while retaining the moiety recognized to be required for efficacy ( $-\text{SO}_n\text{-Z-CO-}$ ), but changing a variable moiety (Y); i.e., adding the end of a second active compound (the  $-\text{CH}_2\text{C}(\text{O})\text{OCH}_3$  from HIII-302) in place of an amine H atom, would have given a new compound for which similar activity to SI-73 would have been expected, including activity against the infections taught. It would also have been obvious to optimize the amount for optimal efficacy against *M. tuberculosis*, as

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described by Townsend (at 2<sup>nd</sup> paragraph of p. 9), for optimizing the treatment method of a human or animal subject infected with *M. tuberculosis*, without harming the subject being treated; administration of an optimized amount (or specific amounts taught) are taken to satisfy the "effective amount" requirement of claims 1 and 15. The motivation would have been the routine optimization of conditions for treating *M. tuberculosis* infection.

With respect to the language of claim 1, "being able to decrease ATP levels...and not kill mammalian cells during the same time period", and the language "overexpression of the b-subunit of ATP synthase", required by claim 15, administration of the optimized effective amount of this compound (or at the same doses as disclosed by applicant (see instant specification, p. 11, last two lines)) would have been expected to have been characterized by each of these claimed limitations, absent evidence to the contrary.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

### **Conclusion**

8. No claim is allowed.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY P. THOMAS whose telephone number is (571)272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy P Thomas/  
Examiner, Art Unit 1628